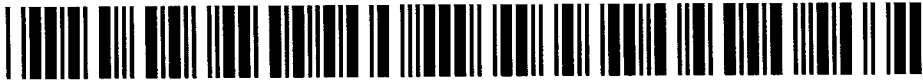


Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12483



5 - SUMMARIES

000001

Document #: [REDACTED]

SSN: [REDACTED]

DATE OF ADMISSION: 07/28/97

HISTORY OF PRESENT ILLNESS: The patient is a 34-year-old female who was previously healthy until this a.m. The patient was at aerobics class when she collapsed. The patient apparently was initially combative and emergency medical services called. The patient was taken to [REDACTED] where computerized tomography scan of the patient's head demonstrated subarachnoid hemorrhage. The patient was subsequently transferred to [REDACTED] and [REDACTED] for further evaluation and treatment.

PAST MEDICAL HISTORY AND PAST SURGICAL HISTORY: Unremarkable.

ALLERGIES: No known drug allergies.

MEDICATIONS: Herbal diet pills.

SOCIAL HISTORY: No tobacco and social alcohol.

PHYSICAL EXAMINATION:

VITAL SIGNS: Blood pressure 102/61, heart rate 122, respiratory rate 24, temperature 35.3.

NEUROLOGIC: Glasgow Coma Scale: E3, M6, V4 for a total score of 13. Pupils equal, round, reactive to light. Extraocular muscles are intact. Facies equal. Tongue midline. The patient was alert and oriented to city, year, president, but not to month or day. The patient was moving all extremities well with excellent strength. This included both upper and lower extremities. No pronator drift was noted.

CHEST: Demonstrated bilateral rales.

CARDIOVASCULAR: Regular rate and rhythm.

ABDOMEN: Benign.

Computerized tomography scan of the patient's head demonstrated significant subarachnoid blood in both sylvian fissures as well as all of the basilar cisterns.

Urine drug screen was positive for amphetamines and barbiturates. Labs from [REDACTED] included sodium of 140, chloride 108, blood urea nitrogen 13, potassium 4.2, carbon dioxide 16, creatinine 1.1, blood sugar 192. White blood cell count 10.4, hemoglobin 13.2, hematocrit 37.8, platelet count 224. Prothrombin time, partial thromboplastin time, and INR 14.7, 31, and 1.4 respectively.

Electrocardiogram showed normal sinus tach at 120.

HISTORY AND PHYSICAL
PAGE 1 OF 2

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CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000002

ARMS #12483

Document #: [REDACTED]

ASSESSMENT AND PLAN:

1. This is a 34-year-old female with subarachnoid hemorrhage, likely aneurysmal in nature. The patient will be admitted to the neurosurgical intensive care unit. Family has already been consented for ventriculostomy as well as four-vessel cerebral angiogram. The patient will also be consented for blood products as well. Internal medicine consult will be obtained for what appears to be neurogenic pulmonary edema. We will also repeat labs including the prothrombin time and partial thromboplastin time as patient will need ventriculostomy, and at the outside hospital they were elevated. Also note the patient should have, at least per instruction was to receive, 10 mg of vitamin K subcutaneously prior to transfer to our hospital.

[REDACTED] M.D.

[REDACTED] MD

Resident

Job #: [REDACTED]

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**HISTORY AND PHYSICAL
PAGE 2 OF 2****CHART COPY**

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Document #: [REDACTED]

SSN: [REDACTED]

DATE OF ASSESSMENT/CONSULTATION: 07/28/97

PULMONARY/INFECTIOUS DISEASE CONSULTATION

HISTORY OF PRESENT ILLNESS: The patient is a 34-year-old Caucasian married female admitted via ambulance from an outside facility. She was reportedly in an aerobics class and during a cooling down/rest period she slumped to the floor and experienced shallow, rapid respirations with possible seizure activity. There was no report of emesis. She was unresponsive to command and combative and agitated. She was incontinent of urine. She was suctioned to clear her airway. She had a head CT scan performed showing a subarachnoid hemorrhage. Her chest x-ray showed pulmonary edema, and she has hypotension with a systolic blood pressure of 85-90. Her electrocardiogram shows sinus tachycardia and a questionable anterior infarct of indeterminate age. She is still agitated but has recently received Ativan. She has oxygen saturations that are low and a pO₂ of 50 on an NRB mask. Her husband states she is in good health. She does not smoke or drink. She exercises regularly.

ALLERGIES: She denies(?) medication allergies but does have some hay fever; she takes no medicines for this. She is allergic(?) to sulfa and aspirin.

REVIEW OF SYSTEMS: Otherwise negative. She has no respiratory problems except for occasional pneumonia but none recently. She has no gastrointestinal or genitourinary problems. No arthritis. No rash.

I discussed ventriculostomy, Swan-Ganz catheter, surgery, need for monitoring and intubation with ventilation with the patient's husband. He is in agreement with all of the above as we deem necessary.

PHYSICAL EXAMINATION:

GENERAL: A well-developed, well-nourished female. She is a bit combative.

HEENT: Optic fundi not visualized.

NECK: Slightly stiff. Thyroid not enlarged. No adenopathy. Neck veins not distended. No bruits.

CHEST: Congested ~~rales~~ and rhonchi bilaterally.

CARDIAC: No murmurs, rubs, or gallops.

ABDOMEN: Soft. No organomegaly. Bowel sounds normal.

EXTREMITIES: No clubbing, cyanosis, or edema.

She is hypotensive. A chest x-ray showed bilateral pulmonary edema; pO₂ of 50.

IMPRESSION:

1. Subarachnoid hemorrhage.
2. Neurogenic pulmonary edema.

CONSULTATION
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8-18-97 JAN(144)
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Document #

3. Respiratory failure.

PLAN: Swan-Ganz catheter, intubate, ventilate, Neo-Synephrine and Lasix.

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CONSULTATION
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Document # [REDACTED]

SSN: [REDACTED]

DATE OF ASSESSMENT/CONSULTATION: 07/29/97

HISTORY OF PRESENT ILLNESS: The patient is a 34-year-old previously healthy female, who collapsed following an aerobics class 7/28. Paramedics were summoned. The patient was initially unresponsive. Bystanders described seizure-like activity. Initial vital signs: Blood pressure systolic 108, heart rate 104, respiratory rate 30. Shortly after arrival, the patient became combative. She was taken to [REDACTED]. On arrival, blood pressure was 110/38, heart rate 104, respiratory rate 32. A computerized tomography scan was performed which revealed a subarachnoid hemorrhage. Initial electrocardiogram demonstrated normal sinus rhythm, left axis deviation, slow precordial R-wave progression, nonspecific anterior ST-T wave changes. Electrolytes were normal. Coagulation studies were normal. The toxic screen demonstrated amphetamines positive, barbiturates positive. The CBC was unremarkable. The patient was transferred to [REDACTED].

Upon arrival, blood pressure was 90/60, heart rate of 100. The patient had rales on examination. The chest x-ray was consistent with pulmonary edema. The patient was intubated. A Swan-Ganz catheter was placed. The initial pulmonary artery wedge was 30. The patient was given Lasix and dobutamine and dopamine instituted. There was marked decreased in the pulmonary artery wedge to 10 to 15. Ventriculostomy was placed. Cerebral angiography demonstrated no evidence of an intracerebral aneurysm.

There is no prior cardiac history. The patient has had no symptoms suggestive of angina pectoris, congestive heart failure, or arrhythmias. The patient had not been on cardiac medications. The patient was taking an "herbal" weight loss preparation consisting of ephedrine and caffeine.

Cardiac risk factors: Five-pack-year smoking history in 1992. No known diabetes, hypertension, or abnormal lipids.

FAMILY HISTORY: Negative for premature coronary artery disease.

PAST MEDICAL HISTORY: Unremarkable.

SOCIAL HISTORY: Married, no children.

PHYSICAL EXAMINATION:

GENERAL: Intubated, ventriculostomy in place, Swan-Ganz catheter via left subclavian. The patient is awake, alert, communicative.

VITAL SIGNS: Blood pressure 105/64, heart rate 124, pulmonary artery wedge 14, CVP 8. Inotropes: Dobutamine 8, dopamine 8.

HEENT: Unremarkable.

NECK: No jugular venous distention. Carotid pulse contours equal without bruits.

CONSULTATION
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000006

CHEST: Clear to percussion and auscultation. No wheezes, rales, or rubs.
HEART: Regular rhythm without palpable heaves or lists. S_1 and S_2 normal. Negative S_3 or S_4 . No murmurs or rubs.
ABDOMEN: Benign, without palpable mass or hepatosplenomegaly.
EXTREMITIES: Without edema. Pulses: 4.

INITIAL LABORATORY DATA: CBC: Hematocrit 38.0, hemoglobin 13.0, WBC 17.1. Electrolytes: 91, 42, K 3.8. Renal - BUN 13, creatinine 0.8. Arterial blood gas - pO_2 138, pCO_2 36, pH 7.41 on FIO_2 60%, INV 10, PEEP 8, tidal volume 750. Chest x-ray - Normal cardiothoracic ratio. Infiltrates consistent with pulmonary edema. Electrocardiogram reveals normal sinus rhythm, minor nonspecific anterior ST-T wave changes, slow precordial R-wave progression. CPK - 401, 603, 622, 419 with 8.8% MB fraction on third sample.

Swan-Ganz data: Cardiac output 7.5, cardiac index 4.8, SPR 672.

INITIAL IMPRESSION:

1. Subarachnoid hemorrhage: No evidence of aneurysm on cerebral angiography. The patient possibly sustained an intracerebral bleed secondary to hypertensive response from ephedrine.
2. Neurogenic pulmonary edema secondary to #1.
3. Cardiac isoenzymes consistent with small myocardial infarction, electrocardiogram does not suggest transmural process.
4. Stable hemodynamics at present.

PLAN:

1. Taper and discontinue dobutamine. Continue dopamine.
2. Maintain pulmonary artery wedge mean above 18.
3. Check troponin I.
4. Repeat electrocardiogram in the a.m.

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CONSULTATION
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